

#### 4-9. SUBMITTING MEDICAL MATERIEL COMPLAINTS

a. All medical materiel complaints, regardless of procurement source, should be submitted on a [Medical or Dental Product Quality Deficiency Report](#) (M/DPQDR). A M/DPQDR should be submitted to report materiel or equipment that has been determined to be harmful and/or defective that may result in death, injury, or illness. M/DPQDRs are categorized into two types:

- Category I: Materiel that has been determined by use or testing to be harmful or defective to the extent that its use has or may cause death, injury, or serious illness.
- Category II: Drugs, devices, supplies, or equipment that is suspected of being harmful, defective, deteriorated, or unsatisfactory because of malfunction or design, which are attributable to faulty materiel, workmanship and/or quality inspection, or performance or are otherwise unsuitable for use.

An M/DPQDR is the customer's way of alerting the system that there is a quality deficiency with a medical or dental product. Deficiencies should be submitted on standard and nonstandard items. It is also the vehicle for submitting Safe Medical Device (SMD) incidents. Examples of discrepancies which should be reported on the M/DPQDR are:

- Wrong or deficient labeling
- Foreign or particulate matter in liquids and solids
- Imperfectly manufactured items which are off-color, off-taste, and off-odor
- Suspected sub-potency or super-potency
- Defective devices
- Pinholes in tubing
- Faulty calibrations
- Systemic equipment failures
- Poor quality products

The submitter will receive a copy of the e-mail that has been sent to DSCP, the Defense Medical Standardization Board (DMSB) and the Services' Medical Logistic Offices at Ft Detrick. Once the form is received, DSCP will assign a Report Control Number (RCN) in the Product Data Reporting and Evaluation Program (PDREP), and respond back to you normally within two days. For more information about the PDREP program go to <http://www.nslcptsmh.navsea.navy.mil/pdrep/pdrep.htm>

b. Report the circumstances of Category I (Type I complaints) immediately to DSCP, through the M/DPQDR or by telephone.

(1) During normal duty hours (0700 - 1700 hours Eastern Time), call the DSCP Emergency Supply Operations Center (ESOC) at  
DSN 444-2111/2112, or commercial 215 737-2112.

A telefax may also be sent to:

Commercial 215 737-2081/7109 or DSN 444-2081/7109.

(2) After duty hours, the numbers called above will automatically transfer to the Staff Duty Officer. If the transfer does not occur or the call is not answered, call the following numbers: DSN 444-2341 or commercial 215 737-2341.

c. The 21 CFR prescribes reporting certain materiel/equipment conditions to the FDA under the Safe Medical Devices Act (SMDA). Logistics personnel will coordinate and provide a copy of the Complaint Form to the Risk Manager as part of the Risk Management Program. The Risk Manager is required under Joint Commission on Accreditation of Healthcare Organization (JCAHO) to review the SMDA information on the Complaint Form and assess the potential risk.